Fact Sheet

Electronic Drug Accountability and Returns Management

The Key to Compliance, Patient Safety and Risk Based Monitoring

eClinical technologies are becoming more commonplace in drug development as biopharma adopts validated methods to maintain compliance while also offering new digital support for patient recruitment, engagement and safety as well as real time data ingestion for critical factors like supply chain forecasting.

A growing number of sponsors are adopting proven electronic technologies that support Drug Accountability and Returns Management, or DARM. Sponsors are using digital solutions for Drug Accountability (DA), because they recognize the significant increase in efficiency and accuracy that these methods provide.

Key takeaways

- The value of electronic drug accountability has been known and published since the early 1990's.
- DARM is closely linked to patient safety.
- During FDA audits, drug accountability is one of the areas with the highest number of findings.
- The biopharma industry's emphasis on analytics, Business Intelligence and Risk Based Monitoring (RBM) needs to include drug accountability in the risk profile — which is not feasible with paper.
- Electronic drug dispensing data is readily available via Interactive Response Technology (IRT) system.

Compliance demands electronic support for drug accountability

There are a number of regulatory requirements that govern the entire drug accountability process. Consider just two from the U.S. Code of Federal Regulations. (There are similar requirements in the ICH Guideline for Good Clinical Practice). The first regulation applies to sponsors: according to 21 CFR 312.57(a),

"A sponsor shall maintain adequate records showing the receipt, shipment, or other disposition of the investigational drug. These records are required to include, as appropriate, the name of the investigator to whom the drug is shipped, and the date, quantity, and batch or code mark of each such shipment."

The information noted as required above is data that is maintained electronically within the IRT system. It is only logical that these very same data fields should be integrated into a DARM system.

Maintaining a second set of paper-based records is inefficient, and it introduces opportunities for errors, omissions and discrepancies. Further, querying and correcting any discrepancies will likely lead to delays in closing out the trial.

The second regulatory requirement applies to investigative sites: 21 CFR 312.62(a) states,

"An investigator is required to maintain adequate records of the disposition of the drug, including dates, quantity, and use by subjects. If the investigation is terminated, suspended, discontinued, or completed, the investigator shall return the unused supplies of the drug to the sponsor, or otherwise provide for disposition of the unused supplies of the drug under 312.59."

Again, most of these data elements are in the IRT system. Creating a redundant paper-based trail can introduce many errors that will be discovered during FDA inspection. Examples of such discrepancies can be found on the following list.

IQVIA IRT DARM REDUCES:

- Incomplete and/or inaccurate dispensing records
- Discrepancies between drug administration forms and accountability records
- Inadequate and inaccurate source documents
- Discrepancies in the amount of medication dispensed to patients

It is clear that creating and maintaining detailed paper records for drug accountability places an unnecessary burden on site personnel — in addition to preventing them from spending more time with patients.

Paper logs also make if more difficult for the Clinical Research Associates (CRAs) responsible. CRAs often raise queries based on these logs. Without electronic DARM, many are reduced to using post-it notes to mark records that appear to contain inconsistencies. The lack of source records makes reconciliation very difficult, and can lead to further chains of queries.

Since FDA inspections lead to findings at 15% to 20% of sites, it is clear that Risk Based Monitoring (RBM) solutions should use Key Risk Indicators (KRIs) that include drug accountability risks. The goal of RBM is to become proactive, identify trends, and address potential risks to remain compliant and ensure patient safety.

Using paper logs that are maintained onsite makes it nearly impossible to create useful KRIs based on drug accountability. By the time a CRA reports potential issues following a site visit, there is little that can be done to rectify the situation.

Paper-based methods of drug accountability can put patients at risk, as FDA findings indicate. If the records are unclear or show discrepancies in dosing or in the amount of medication given to a patient, the site and sponsor cannot be sure the patient received the right medication and the right amount. And, if there are issues with the amount returned by the patient, no one can be certain that the patient was compliant. The need for a better solution is obvious.

The simplicity and utility of electronic DARM

As noted, a trial's IRT system already contains much of the data that must be logged for the entire DARM process. IRT tracks drug from Qualified Person (QP) release through to dispensing. It records units by warehouse, depot, site location, batch, bulk lot, packaging step, label group, and patient allocation. The system also contains details on the packaging types available for each medication, whether it is capsules, liquid measures or other units that must be reconciled.

By using these features, DARM functionality can be added for a complete system that captures the return of the drug from the patient and follows it through to destruction, either at the site or the depot. The IRT system already automatically time-stamps dispensing information.

DARM — Fully configured to address each trial's specific requirements

For unique trial needs, just like the IRT system, a DARM system can be fully configured to the needs of each trial. For example, in some regions destruction may be done at the investigative site, while in other regions medication may be returned to the depot for destruction.

There are other areas where configuration for local needs must be considered. The system should have the flexibility to easily set up each site and/or region according to the local SOPs, regulatory demands and other requirements.

IQVIA IRT DARM:

- Flags entries that do not adhere to protocol
- Enforces compliance by mandating that staff write summary statements for potential protocol deviations
- Creates an audit trail with digital signatures that helps preserve the integrity of the trial data

Electronic DARM also simplifies life for CRAs by allowing them to review accountability logs remotely prior to site visits. This enables CRAs to issue queries and reconcile discrepancies in advance, so that during site visits, they can focus on trial procedures and site interactions that truly improve quality rather than reviewing tedious paper trails.

And unlike antiquated paper processes, the digital solutions are designed with safeguards to reduce the risk of human error.

The electronic data can also be used to manage the returns of unused or partially used drug kits as well as reconciling figures for supplies that were reported lost or damaged. In fact, the DARM system can generate the actual drug returns, packaging and shipping forms required and can track the destruction certificates. This allows a user to see the full lifecycle of a kit from release to destruction, all in one central location.

There are additional important benefits of having all relevant data in a central location in real time. The central data store and audit trails provide full support for site inspections. They also provide valuable data that can be used in analytics supporting RBM and risk-mitigation strategies. And, DARM reports and dashboards allow trial managers to be proactive if they spot negative trends.

Keeping patients engaged and safe

Finally — and most important — are the considerations regarding the patient. By electronically maintaining the complete chain of custody from depot-to-patient-to destruction, the DARM system greatly reduces opportunities for human error and provides tools and assistance to help ensure accuracy in all patient and medication records.

In turn, clear and error-free logs lead to more accurate indications of patient compliance and treatment. It is time for our industry to move forward to bring drug accountability into the 21st century.

PROVEN ELECTRONIC DARM BENEFITS:

- Improved patient safety
- Enhanced RBM and quality
- Reduced site burden
- Decreased risk of inspection and audit findings
- Cost savings from closing out trials faster

Additionally, since DARM functionality is already fully integrated into solutions that sites and sponsors already use via an IRT system, DARM deployment and setup requires minimal efforts. Now is the time for biopharma to adopt electronic drug accountability.

IQVIA IRT, an IQVIA Business, would welcome the opportunity to speak with your organization about how our unparalleled approach to building IRT systems, founded on quality, flexibility and expertise can benefit your organizations clinical programs. To request more information, click here.

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